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PATENT !

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of: RONALD A. SCHACHAR  
United States Serial No.: 09/556,143  
Filed: April 21, 2000  
Title: SEGMENTED SCLERAL BAND AND TREATMENT OF  
PRESBYOPIA AND OTHER EYE DISORDERS  
Examiner: David M. Shay  
Art Group Unit: 3739

**MAIL STOP APPEAL BRIEFS - PATENTS**  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

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TECHNOLOGY CENTER R3700

Sir:

**APPELLANT'S REPLY BRIEF UNDER 37 C.F.R. §1.193(b)**

This Reply Brief is in furtherance of the Notice of Appeal filed in this application on June 24, 2003 and received in the U.S. Patent and Trademark Office on July 1, 2003. This Reply Brief is filed in response to the Examiner's Answer dated February 2, 2004.

The fees required under 37 C.F.R. §1.17(c), and any required petition for extension of time for filing this appeal brief and fees for any such extension of time, are dealt with in the accompanying transmittal letter.

This brief is transmitted in triplicate (37 C.F.R. §1.192(a)).

This brief contains these items under the following headings and in the order set forth below  
(37 C.F.R. §1.192(c)):

- I REAL PARTY IN INTEREST
- II RELATED APPEALS AND INTERFERENCES
- III STATUS OF CLAIMS
- IV STATUS OF AMENDMENTS
- V SUMMARY OF INVENTION
- VI ISSUES
- VII GROUPING OF CLAIMS
- VIII ARGUMENTS
- IX APPENDIX OF CLAIMS INVOLVED IN THE APPEAL

The final page of this brief before the beginning of the Appendix of Claims bears the attorney's signature.

I REAL PARTY IN INTEREST (37 C.F.R. §1.192(c)(1))

The real party in interest in this appeal is RAS Holding Corporation.

II RELATED APPEALS AND INTERFERENCES (37 C.F.R. §1.192©)(2))

There are no other appeals or interferences that will directly affect, be directly affected by, or have a bearing on the Board's decision in this appeal.

III STATUS OF CLAIMS (37 C.F.R. §1.192(c)(3))

The status of the claims in this application are:

A. TOTAL NUMBER OF CLAIMS IN APPLICATION

There are fourteen (14) pending claims in the application (Claims 31-44).

B. STATUS OF ALL THE CLAIMS

1. Claims previously canceled: Claims 1-30.
2. Claims withdrawn from consideration but not canceled: Claims 45-48.
3. Claims pending: Claims 31-44.
4. Claims allowed: Claims 40-44.
5. Claims rejected: Claim 31-49.

C. CLAIMS ON APPEAL

The claims on appeal are 31-39.

IV STATUS OF AMENDMENTS (37 C.F.R. §1.192(c)(4))

No amendments were filed after the claims were finally rejected by the Office Action dated March 24, 2003.

V SUMMARY OF INVENTION (37 C.F.R. §1.192(c)(5))

The present invention relates to the treatment of presbyopia and other eye disorders. (*Substitute specification, Page 6, Lines 21-23*). Presbyopia is the universal decrease in the amplitude of accommodation of the eyes that is typically observed in individuals over forty years of age. (*Substitute specification, Page 4, Lines 20-22*). In an individual who has normal vision, the ability to focus on near objects is gradually lost, and the individual then needs glasses for tasks requiring near vision, such as reading. (*Substitute specification, Page 4, Line 22 - Page 5, Line 2*).

In the present invention, presbyopia is treated by increasing the amplitude of accommodation of the eye by increasing the effective working distance of the ciliary muscle in the presbyopic eye. (*Substitute specification, Page 6, Lines 21-23*). The effective working distance of the ciliary muscle is increased by expanding the sclera in the region of the ciliary body. (*Substitute specification, Page 10, Lines 13-18*). This expansion may be accomplished by weakening the sclera of the eye using laser irradiation. (*Substitute specification, Page 23, Lines 10-14*).

The present invention comprises an apparatus and method for increasing the accommodation of an eye. (*Substitute specification, Page 1, Lines 20-22*). One advantageous embodiment of the method of the present invention comprises a step of weakening the sclera of the eye through laser irradiation in the region of the ciliary body of the eye to thereby increase the effective working distance of the ciliary muscle. (*Substitute specification, Page 25, Lines 4-16*). One advantageous embodiment of the apparatus of the present invention comprises a laser that is operable to provide laser irradiation to weaken the sclera of the eye in the region of the ciliary body of the eye to thereby increase the effective working distance of the ciliary muscle. (*Substitute specification, Page 23, Lines 10-14*).

VI ISSUES (37 C.F.R. §1.192(c)(6))

Whether the Examiner erred in finally rejecting Claims 31-39 under 35 U.S.C. § 102(b) as being anticipated by *Fankhauser*.

VII GROUPING OF CLAIMS (37 C.F.R. §1.192(c)(7))

The Appellant does not make a statement under 37 C.F.R. §1.192(c)(7) regarding the grouping of claims.

## VIII ARGUMENTS

In the Examiner's Answer dated February 2, 2004 the Examiner allowed Claims 40-44. The Examiner also withdrew an enablement rejection because the original specification "does provide support for the use of a laser as claimed." (February 2, 2004 Examiner's Answer, Page 4, Lines 2-3). The Examiner also stated that "However, the substitute specification includes matter not disclosed in Patent Number 5,354,331 and as such entry thereof is still denied." (February 2, 2004 Examiner's Answer, Page 4, Lines 4-5). The Examiner did not identify the matter to which the Examiner was referring. The Appellant respectfully traverses this assertion of the Examiner and respectfully traverses the Examiner's denial of the entry of matter that was in the substitute specification.

The Examiner continued to reject Claims 31-39 under 35 U.S.C. § 102(b) as being anticipated by United States Patent No. 4,391,275 to *Fankhauser*.

Section 102, in pertinent part, provides that a "person shall be entitled to a patent unless . . . (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States." It is axiomatic that anticipation of a claim under § 102 can be found only if the prior art reference discloses every element of the claim. *See, In re King*, 231 U.S.P.Q. 136, 138 (Fed. Cir. 1986) (citing with approval, *Lindemann Maschinenfabrik v. American Hoist and Derrick*, 221 U.S.P.Q. 481, 485 (Fed.Cir. 1984)).

Independent Claim 31 reads as follows:

31. A laser operable to weaken the sclera of an eye in the region of the ciliary body with laser irradiation to thereby increase the effective working distance of the ciliary muscle of the eye. (Emphasis added).

A determination of anticipation, with respect to Claim 31 requires that each feature claimed therein be described in *Fankhauser* in sufficient detail to enable one of ordinary skill in the art to make and practice the claimed invention. Appellant respectfully asserts that the above emphasized limitations of Claim 31 are not disclosed, suggested or even hinted at in the *Fankhauser* reference. In particular, Claim 31 recites the limitation of “weakening the sclera of the eye with laser irradiation to increase the effective working distance of the ciliary muscle of the eye.” This limitation is not disclosed, suggested, or even hinted at in the *Fankhauser* reference.

*Fankhauser* discloses a method that uses laser radiation to perforate the tissues of an eyeball in order to reduce an increased level of intra-ocular pressure in the eye due to glaucoma. There is nothing in the *Fankhauser* reference that discloses, suggests or even hints at the invention disclosed and claimed by the Appellant. Simply stated, Claim 31 is not anticipated by the *Fankhauser* reference. The Appellant respectfully submits that Claim 31 is patentable.

The Examiner stated that the *Fankhauser* laser is operable (i.e., can be operated to) weaken the sclera “for example by moving the patient a fraction of a millimeter closer to the laser. Thus causing ablation or destruction of the sclera.” (February 2, 2004 Examiner’s Answer, Page 4, Lines 19-21). But *Fankhauser* does not disclose the concept of “causing ablation or destruction of the sclera.” *Fankhauser* indicates that while the “cells of the external wall of the canal of Schlemm S” are destroyed, the “collagen fibres of the sclerotic layer have practically not suffered.”

(*Fankhauser*, Column 6, Lines 3-13). The concept of ablating or destroying the sclera is disclosed in and provided by the Appellant's invention. *Fankhauser* does not disclose "moving the patient a fraction of a millimeter closer to the laser" in order to ablate or destroy the sclera.

Further, the Examiner noted that the "density of radiated energy causes ionization of the propagation medium" and concluded that "Thus the density will cause ionization and tissue ablation in the sclera if the beam is directed thereto." (Emphasis added) (February 2, 2004 Examiner's Answer, Page 5, Lines 1-3). The Appellant respectfully submits that the concept of directing laser radiation toward the sclera of an eye is disclosed in and provided by the Appellant's invention. *Fankhauser* does not disclose the concept of "directing a laser beam to the sclera in order to ablate or destroy the sclera." If *Fankhauser* did disclose this concept then there would be no reason to use the phrase "if the beam is directed thereto." And, as previously mentioned, the *Fankhauser* method leaves the sclera practically undamaged.

Therefore the Appellant respectfully submits that the *Fankhauser* reference does not disclose all of the elements of Claim 31 and does not anticipate Claim 31.

Appellant notes that Claims 32-39 depend from Claim 31 and contain all of the unique and novel limitations contained in Claim 31. This being the case, Claims 32-39 are also patentable over the *Fankhauser* reference.



**SUMMARY**

For the reasons given above, the Appellant respectfully requests reconsideration and allowance of the claims and that this patent application be passed to issue.

Respectfully submitted,

DAVIS MUNCK, P.C.

Date: April 2, 2004



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IX, APPENDIX OF CLAIMS INVOLVED IN THE APPEAL (37 C.F.R. §1.192(c)(9))

The text of each claim involved in the appeal is as follows:

31. A laser operable to weaken the sclera of an eye in the region of the ciliary body with laser irradiation to thereby increase the effective working distance of the ciliary muscle of the eye.

32. The laser set forth in Claim 31 operable to weaken the sclera of the eye in the region of the ciliary body by abrading the sclera with laser irradiation.

33. The laser set forth in Claim 31 operable to weaken the sclera of the eye in the region of the ciliary body by ablating the sclera with laser irradiation.

34. The laser set forth in Claim 31 operable to weaken the sclera of the eye in the region of the ciliary body by incising the sclera with laser irradiation.

35. The laser set forth in Claim 31 operable to weaken the sclera of the eye in the region of the ciliary body by incising the sclera at select angles with laser irradiation.

36. The laser set forth in Claim 31 operable to weaken the sclera of the eye in the region of the ciliary body by decomposing partially collagen fibers in the sclera.

37. The laser set forth in Claim 31 wherein said laser is one of a carbon dioxide laser, a helium-neon laser, a helium-cadmium laser, an argon ion laser, a krypton ion laser, a xenon laser, a nitrous oxide laser, iodine laser, a holmium doped yttrium-aluminum garnet laser, an excimer laser, a chemical laser, a harmonically oscillated laser, a dye laser, a nitrogen laser, a neodymium laser, an erbium laser, a ruby laser, a titanium-sapphire laser and a diode laser.

38. The laser set forth in Claim 31 wherein said laser uses one of ionizing radiation and non-ionizing radiation to weaken the sclera of an eye in the region of the ciliary body, thereby increasing the effective working distance of the ciliary muscle of the eye.

39. The laser set forth in Claim 31 operable to increase the amplitude of accommodation of the eye.

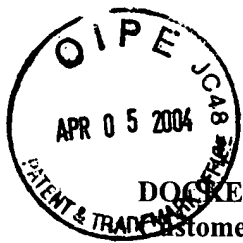
40. A method of operating a laser to treat one of presbyopia, hyperopia, primary open angle glaucoma and ocular hypertension, said method comprising the step of irradiating the sclera of an eye in the region of the ciliary body to thereby weaken the sclera of the eye and increase the effective working distance of the ciliary muscle of the eye.

41. The method of operation set forth in Claim 41 wherein said step of irradiating the sclera of the eye in the region of the ciliary body further comprises the step of abrading the sclera with laser irradiation.

42. The method of operation set forth in Claim 41 wherein said step of irradiating the sclera of the eye in the region of the ciliary body further comprises the step of ablating the sclera with laser irradiation.

43. The method of operation set forth in Claim 41 wherein said step of irradiating the sclera of the eye in the region of the ciliary body further comprises the step of incising the sclera with laser irradiation.

44. The method of operation set forth in Claim 41 wherein said step of irradiating the sclera of the eye in the region of the ciliary body further comprises the step of decomposing partially collagen fibers in the sclera.



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CERTIFICATE OF MAILING BY FIRST CLASS MAIL

Sir:

The undersigned hereby certifies that the following documents:

1. Appellant's Reply Brief Under 37 C.F.R. §1.193(b) (in triplicate); and
2. Postcard

relating to the above application, were deposited as "First Class Mail" with the United States Postal Service, addressed to: MAIL STOP APPEAL BRIEF - PATENTS, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on April 2, 2004.

Date: 4/2/04

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